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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,563	MURRAY ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7,8 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7,8 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 3/3/05. The amendment filed 3/3/05 is acknowledged. The amendment has been entered. Claims 1, 2, 4, 5, 7, 8 and 21-24 are currently pending in the application and are examined herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims encompass, a method comprising delivering mRNA to cells of a wound and potentiating an increase in protein synthesis "from endogenous cellular mRNA in the wound from the delivered mRNA" (See claims 21 and 22; emphasis added). The phrase "from the delivered mRNA" renders the claims indefinite because it is unclear how "from the delivered mRNA" relates to the rest of the claim. As such it is unclear what is intended to be "from the delivered mRNA". Claims 23 and 24 depend on claim 21 and are rejected for the same reason.

In the interest of compact prosecution, the instant claims will be interpreted such that the phrase "from the delivered mRNA" has no weight (that is, the claims will be examined as if the phrase "from the delivered mRNA" was not part of the claim).

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure

of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. (Emphasis added).

The instant claims are drawn to a method of augmenting wound healing by delivering a mRNA functionally related to protein production and potentiating an increase in protein synthesis in cells of the wound (claim 21); "wherein said delivering step further includes" delivering mRNA encoding a translational regulatory protein (claim 23); "wherein said delivering step further includes" delivering mRNA encoding the translation initiation factor eIF4E (claim 24).

It is noted that the phrase "wherein said delivering step further includes" is interpreted as indicating an additional element that is included in the delivery step. Therefore, the claims encompass a method comprising the delivery of three mRNAs (the mRNA of claim 21, the mRNA of claim 23 and the mRNA of claim 24).

The specification has disclosed a method of augmenting wound healing comprising the delivery of a mRNA encoding EGF and a mRNA encoding eIF4E. Therefore, the specification has disclosed a method of augmenting wound healing by delivering two mRNAs, but the specification does not appear to disclose a mRNA encoding three mRNAs, as is required by claim 24. It is noted that claim 24 depends from claim 23 and 21, as such claims 21 and 23 must encompass delivering three mRNAs as well.

It is noted that the Applicants have not indicated the exact location in the specification where the support for the instant amendment(s) can be found. A thorough search of the specification was performed; however, no support for the amended subject matter could be found. Should Applicants disagree, they are asked to indicate by specific page and line number where in the specification support for the amendment can be found.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, the instant claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

It is noted that should applicants change claim 24 such that it only narrowed the mRNA of claim 23 to a mRNA encoding eIF4E would obviate this rejection, as the specification does have support for administering two mRNAs one encoding EGF and a mRNA encoding eIF4E. An example of an a possible amendment would be to change claim 24 from "The method of claim 23 wherein said delivering step further includes directly intracellularly delivering mRNA encoding the translation initiation factor eIF4E..." to, "The method of claim 23 wherein said mRNA encodes the translation initiation factor eIF4E..."

Claims 1, 2, 4, 5, 7, 8 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

> A method for augmenting the healing of a wound in a subject having said wound by administering mRNA encoding a growth factor either alone or in combination with a mRNA encoding eIF4e directly to cells of the wound, wherein administering said mRNA(s) to said cells transiently increases protein synthesis of said growth factors in said cells resulting in augmenting the healing of said wound;

does not reasonably provide enablement for the full scope encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,
"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

It is noted that claim 5 indicates that the method (of claim 1) is useful for wound healing. Therefore, claims 1, 2 and 4, although they are broad, must encompass wound healing. Claims 7 and 8 are drawn to methods of augmenting transient protein synthesis of a cell in need of increased protein synthesis. Looking to the specification for guidance, the only cells described in the specification as in need of increased protein synthesis are wound cells. As such, claims 7 and 8 must also encompass wound healing. Claims 21-24 explicitly indicate that the method is a method of augmenting wound healing. As such, all of the claims encompass augmenting wound

healing by delivering mRNA(s) encoding protein(s) that are functionally related to protein synthesis. Therefore, the nature of the invention is to augment wound healing by administering mRNA(s) encoding protein(s) to the cells of the wound such that the mRNA(s) express the mRNA(s) in the cells and augment healing of the wound.

The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims are very broad and encompass augmenting wound healing by administering (1) mRNA encoding an initiation factor functionally related to protein synthesis (e.g., see claim 1), (2) mRNA encoding a translational regulatory protein functionally related to protein production (e.g., see claim 7), (3) mRNA functionally related to protein production (e.g., see claim 21), (4) mRNA functionally related to protein production and mRNA encoding a translational regulatory protein (e.g., see claim 23), and (5) mRNA functionally related to protein production, mRNA encoding a translational regulatory protein, and mRNA encoding the translational regulatory protein eIF4E (e.g., see claim 24). With respect to the definition of mRNA functionally related to protein synthesis, and mRNA encoding a translational regulatory protein functionally related to protein production, it is noted that the specification discloses:

> "A translation initiation factor is a product that initiates or begins protein synthesis. The translation initiation factor can be the factor specifically disclosed herein, namely, elF4E, or it can be any chemical that is capable of initiating protein synthesis." (See page 10; Emphasis added)
>
> "The mRNA of the present invention functionally relates to protein synthesis. More specifically, the mRNA encodes for proteins that are desired to be upregulated in a cell.

> In other words the mRNA encodes proteins that are required to be expressed in a cell. For example, the mRNA can encode for proteins necessary for wound healing, to promote cell death, or any other desired effect that is based upon or relies upon protein synthesis." (See page 11)

As such, the claims are very broad and encompass a vast number of different mRNAs, including mRNAs that are in any way functionally related to protein synthesis, as well as mRNAs encoding initiation factors wherein the initiation factor can be ANY factor that is capable of initiating protein synthesis (i.e., the claims are not be limited to eukaryotic translation initiation factors such as eIF4E, but encompass ANYTHING that can initiate protein synthesis such as growth factors, transcription factors, or other proteins necessary for wound healing).

Therefore, in the most general sense, the claims encompass a method comprising administering mRNA encoding a polypeptide that increases protein synthesis in the cell, wherein the mRNA can encode ANY protein that is known to increase protein synthesis or ANY protein that is necessary for wound healing.

The unpredictability of the art and the state of the prior art

The general method of administering a mRNA encoding a protein of interest to a cell using gene gun particle acceleration was known in the art (e.g., see Qui et al., 1996, cited by Applicants). Qui et al. specifically teaches delivering a mRNA encoding human growth hormone (GH) to cells in vitro and in vivo such that the mRNA expresses the GH protein in the cells. Furthermore, a number of different growth factors were recognized as proteins which are necessary for wound healing. Specifically, the prior art indicates that human growth hormone, IGF-I, IGF-II, PDGF, bFGF, TGF-beta, EGF, TGF-alpha, TNF-alpha and SF-HGF (e.g., see Steenos, 1994 abstract, Figure 2, p. 97-101, etc.). Specifically, Steenos teaches,

> "For the last decade, that growth factors are essential for regulating the cellular events involved in the formation of granulation tissue and in wound healing. Recently, clinical trials were initiated to study the wound healing effects of applying growth factors and growth hormone to human wounds." (See p. 95, abstract); and,
>
> "About 30 growth factors have been identified, but not all are of importance in wound healing." (See p. 95, second column).

Steenos clearly indicates that specific factors are recognized as necessary for wound healing, but not all factors are necessary for wound healing. As such, not all mRNAs functionally related to protein synthesis can be considered as necessary and useful for wound healing. Only the factors that are disclosed in the art and those which have been shown to be useful by the working examples of the specification.

It is noted that gene therapy method for treating wounds wherein nucleic acid encoding EGF is administered to wound cells was also known in the art (e.g., see Andree et al.-cited in IDS).

Furthermore, translation regulatory proteins which increase the synthesis proteins in a cell were also known in the art (e.g., see Hiremath et al.—cited in IDS).

Working Examples and Guidance in the Specification

The specification discloses working examples wherein specific mRNA encoding specific proteins (i.e., EGF and eIF4E) are delivered to wounds cells for augmenting wound healing. Specifically, the specification indicates a method that can augment the healing of a wound by administering a mRNA encoding a growth factor (specifically EGF) to the cells of a wound, resulting in increased wound healing. Also disclosed is a method that can augment the healing of a wound by administering a mRNA encoding a growth factor (specifically EGF) in

combination with a mRNA encoding the translation initiation factor eIF4E to the cells of a wound, resulting in increased wound healing.

Quantity of Experimentation

Considering the limited amount of working examples and guidance provided by the specification, in view of the breadth of claims, additional experimentation would be required in order to practice the instant claimed methods to their full scope. For instance, additional experimentation would be required with respect to the number of different mRNAs encompassed by the claims. The claims encompass administering any mRNA functionally related to protein synthesis to cells for augmenting wound healing. As indicated herein, the claims encompass vast number of different mRNAs, including mRNAs encoding anything that result in protein synthesis in a cell (such as non-growth factor proteins). However, based on the prior art, one of skill in the art would recognize that not all mRNAs that are functionally related to protein synthesis would be useful for treating wounds. Therefore, an enormous amount of additional experimentation would be required to identify the mRNAs that are useful for treating wound healing and the ones which are not useful. The additional experimentation would require an enormous amount of trial and error experimentation. Furthermore, the identification of new wound healing factors is considered an inventive step, and not merely a matter of routine experimentation. As such the amount of additional experimentation required to practice the claims to their full scope is undue.

Level of the skill in the art

The level of the skill in the art is deemed to be high.

Conclusion

Considering the breadth of the claims, the teachings of the prior art, the lack of working examples and guidance in the specification, and the high degree of skill required as a whole, it is concluded that the amount of experimentation required to perform the broadly claimed invention to the full scope encompasses by the claims is undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Qui et al. (Gene Therapy, 1996, cited by Applicants in IDS received 7/1/04).

It is noted that the claims encompass a method comprising administering a mRNA encoding an initiation factor functionally related to protein synthesis (e.g., see claim 1).

The instant claims encompass "mRNA encoding an initiation factor functionally related to protein synthesis". Looking to the specification for guidance, it is noted that pages 10 and 11 of the specification disclose:

> "A translation initiation factor is a product that initiates or begins protein synthesis. The translation initiation factor can be the factor specifically disclosed herein, namely, elF4E, or it can be any chemical that is capable of initiating protein synthesis." (See page 10; Emphasis added)
>
> "The mRNA of the present invention functionally relates to protein synthesis. More specifically, the mRNA encodes for proteins that are desired to be upregulated in a cell. In other words the mRNA encodes proteins that are required to be expressed in a cell.

> For example, the mRNA can encode for proteins necessary for wound healing, to promote cell death, or any other desired effect that is based upon or relies upon protein synthesis." (See page 11)

As such, the claims are very broad and encompass a vast number of different mRNAs, including mRNAs that are in any way functionally related to protein synthesis, as well as mRNAs encoding initiation factors wherein the initiation factor can be ANY factor that is capable of initiating protein synthesis (i.e., the claims are not limited to eukaryotic translation initiation factors such as eIF4E, but encompass ANYTHING that can initiate protein synthesis such as growth factors, transcription factors, etc.).

Qui teaches a method comprising delivering a mRNA encoding human Growth Hormone (GH) to cells in vitro and vivo wherein the mRNA is delivered by gene gun delivery (it is noted that gene gun delivery delivers a nucleic acid molecule by particle acceleration) (e.g., see abstract; p. 262, second column, last paragraph; p. 267, second paragraph; etc.). It is noted that growth factors, including growth hormone, are well recognized in the art as factors which activate of cellular proliferation and gene expression in cells.

Given the broadest reasonable interpretation of the claims in view of the definitions provided by the specification (as indicated above), a mRNA encoding Growth Hormone is a mRNA encoding an initiation factor functionally related to protein synthesis.

Therefore, Qui anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 7, 8, 21, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qui et al. (Gene Therapy, 1996, cited by Applicants in IDS received 7/1/04) in view of Steenos (Scand. Journal Plastic Reconst. Hand Surgery, 1994; Vol. 28, pages 95-105).

It is noted that the claims encompass a method comprising administering a mRNA encoding an initiation factor functionally related to protein synthesis (e.g., see claim 1).

The instant claims encompass "mRNA encoding an initiation factor functionally related to protein synthesis" (e.g., see claim 1), "mRNA encoding a translational regulatory protein functionally related to protein production" (e.g., see claim 7), and, "mRNA functionally related to protein production". Looking to the specification for guidance, it is noted that pages 10 and 11 of the specification disclose:

> "A translation initiation factor is a product that initiates or begins protein synthesis. The translation initiation factor can be the factor specifically disclosed herein, namely, elF4E, or it can be any chemical that is capable of initiating protein synthesis." (See page 10; Emphasis added)
>
> "The mRNA of the present invention functionally relates to protein synthesis. More specifically, the mRNA encodes for proteins that are desired to be upregulated in a cell. In other words the mRNA encodes proteins that are required to be expressed in a cell. For example, the mRNA can encode for proteins necessary for wound healing, to promote cell death, or any other desired effect that is based upon or relies upon protein synthesis." (See page 11)

As such, the claims are very broad and encompass a vast number of different mRNAs, including mRNAs that are in any way functionally related to protein synthesis, as well as mRNAs encoding initiation factors wherein the initiation factor can be ANY factor that is capable of initiating protein synthesis (i.e., the claims are not limited to eukaryotic translation initiation factors such as eIF4E, but encompass ANYTHING that can initiate protein synthesis such as growth factors, transcription factors, etc.).

Qui teaches the general concept that mRNA encoding a gene of interest can be delivered to a cell (in vitro and in vivo) using gene gun particle acceleration such that the mRNA is delivered into the target cell and the gene of interest encoded by the delivered mRNA is expressed in the cell. Therefore it would have been obvious to one of skill in the art at the time of filing that the method taught by Qui could be used to deliver and express ANY gene of interest in a cell.

Specifically, Qui teaches a method comprising delivering a mRNA encoding human Growth Hormone (GH) to cells in vitro and vivo wherein the mRNA is delivered by gene gun delivery (it is noted that gene gun delivery delivers a nucleic acid molecule by particle acceleration) (e.g., see abstract; p. 262, second column, last paragraph; p. 267, second paragraph;

etc.). It is noted that growth factors, including growth hormone, are well recognized in the art as factors which activate of cellular proliferation and gene expression in cells.

Given the broadest reasonable interpretation of the claims in view of the definitions provided by the specification (as indicated above), a mRNA encoding Growth Hormone is a mRNA encoding an initiation factor functionally related to protein synthesis.

Steenos teaches that human GH is a growth factor that is useful for treating wounds. Specifically, Steenos teaches,

> "For the last decade, that growth factors are essential for regulating the cellular events involved in the formation of granulation tissue and in wound healing. Recently, clinical trials were initiated to study the wound healing effects of applying growth factors and growth hormone to human wounds." (See p. 95, abstract); and,

> "Growth hormone has an anabolic action in the stimulation of protein synthesis and also effects the metabolism of carbohydrates, lipids, minerals and fluids... From the wound healing aspect, increased protein synthesis may be important both in improving healing and in decreasing healing time." (See p. 100, second column, second to last paragraph); and,

> "Systemic treatment with growth hormone in rats increased mechanical strength after four days in incisional wounds, and reversed the inhibition created by starvation...Growth hormone applied locally in wound cylinders increased amounts of granulation tissue by 50% and increased IGF-I mRNA concentrations in the tissue, suggesting that IGF-I is a mediator of the effect of growth hormone in wound healing... A clinical trial of 29 patients with chronic leg ulcers showed that topically applied growth hormone significantly reduced the size of the wound compared with control wounds. (See p. 101, first two paragraphs).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Qui and Steenos to create a method of treating wounds (which includes cells that are in need of increased protein synthesis) by using the method taught by Qui such that the method delivers the mRNA encoding human GH to cells of a wound in order to augment wound healing with a reasonable expectation of success.

The motivation to combine the references to create claimed invention is provided by Steenos who teaches that it is desirable to deliver human growth hormone to wound cells for augmenting healing of the wound.

Response to Arguments

It is noted that new rejections under 35 USC 112, 102 and 103 have been set forth herein. Furthermore, the previous rejection under 35 USC 102 and 35 USC 112, 1st paragraph (written description) have been withdrawn, and the rejection of claims under 35 USC 112, 1st paragraph (scope of enablement) has been modified, such that it is considered a new rejection. Applicants' arguments address the previous rejections of claims. Since all of the claims are rejected by the new rejections set forth herein, Applicants arguments are moot. Furthermore, since the new grounds of rejection have been set forth, the instant Action is Non-Final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
Art Unit 1635

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER